AFFIDAVIT OF BETH ANN IRVINE IN SUPPORT OF CRIMINAL COMPLAINT

I, Assistant Special Agent in Charge Beth Ann Irvine, being duly sworn, state:

INTRODUCTION

1. I am a Special Agent for the United States Department of Health and Human Services, Office of the Inspector General, Investigations Unit ("HHS-OIG") currently assigned to the Boston, Massachusetts Field Office. I am assigned to a squad that investigates health care fraud. I have a bachelor's degree in accounting and a master's degree in business administration. I am also certified public accountant, with a current license in Massachusetts.

2. I am an investigative or law enforcement officer of the United States within the meaning of 18 U.S.C. § 2510(7), in that I am empowered by law to conduct investigations of, and to make arrests for, offenses enumerated in 18 U.S.C. § 2516.

3. I submit this affidavit for the limited purpose of establishing probable cause to support a criminal complaint charging MARK THOMAS MOFFETT with conspiracy to commit wire fraud, in violation of 18 U.S.C. § 371, and wire fraud, in violation of 18 U.S.C. § 1343.

4. The facts in this affidavit come from my personal involvement in this investigation, interviews with witnesses, and my review of documents, records, and information provided by others. This affidavit does not contain every fact learned during the investigation in this case, but only the information needed to support issuing the complaint.

BACKGROUND

5. MARK THOMAS MOFFETT ("MOFFETT") is a 45-year-old man who resides in Springfield, Illinois.

6. At all relevant times, the Company was a pharmaceutical company with a principal place of business located in Cambridge, Massachusetts.

7. The Illinois Practice is a cardiology practice in Illinois with multiple locations, including in Mattoon and in Springfield. At its Mattoon location, the Illinois Practice employed Doctor A, the Physician Assistant, and Manager. At its Springfield location, the Illinois Practice employed Doctor B and Nurse A and Nurse B. The Illinois Practice also employed Doctor C.

8. Beginning in January 2013, the Company marketed the Cholesterol Drug, which the United States Food and Drug Administration ("FDA") approved for use only in patients with a rare genetic disease, homozygous familial hypercholesterolemia ("HoFH"), because such patients do not adequately respond to conventional cholesterol-lowering therapies, such as statins or fibrates.

9. At all relevant times, the Cholesterol Drug cost roughly $330,000 per patient per year.

10. The Company marketed the Cholesterol Drug nationally using regional sales representatives. The Company paid its sales representatives a base salary, plus a new prescription bonus of $9,000, plus maintenance bonuses if patients receiving the Cholesterol Drug remained on therapy over time.

11. Use of the Cholesterol Drug has significant risks, including liver toxicity and severe gastrointestinal distress.

12. Due to the risks associated with the Cholesterol Drug, the FDA required the Company to implement a Risk Evaluation Mitigation Strategy ("REMS"). The REMS required prescribers to be educated on the risks of the Cholesterol Drug, to register with the REMS program, and to attest on all prescriptions that the relevant patient had a "clinical or laboratory diagnosis" consistent with HoFH. The REMS also restricted distribution of the drug to a single specialty pharmacy.

13. The Pharmacy, located in St. Louis, Missouri, is the specialty pharmacy used by the Company to distribute the Cholesterol Drug. The Pharmacy did not process prescriptions for the

Cholesterol Drug from prescribers who were not enrolled in the REMS program and, in the ordinary course, would not ship the Cholesterol Drug unless and until payment for the Cholesterol Drug had been approved by a health insurance plan.

14. Health insurance plans often required prior authorization of prescriptions for the Cholesterol Drug due to its cost and safety concerns. Such prior authorizations often required prescribers to verify that patients for whom the Cholesterol Drug had been prescribed actually had been diagnosed with HoFH. Health insurance plans also required prescribers to provide indicia of a correct HoFH diagnosis, including, in many cases, evidence of a genetic test or of a skin fibroblast test or of cholesterol levels both in the patient and in the patients' parents. Some health insurance plans also considered clinical information regarding other physical manifestations of HoFH, such as corneal arcus (fat around the cornea) or xanthomas (fatty deposits, typically on tendons).

15. To facilitate the processing of insurance claims for patients and to coordinate patient support services (diet and nutrition), the Company established Patient Access Program, in its headquarters in Cambridge, Massachusetts. Patient Access Program employed customer service representatives who could assist patients and doctors offices with claims for the Cholesterol Drug, but only after patients consented in writing to the disclosure of their private health information to the Company.

16. Starting in January 2014, MOFFETT worked as a sales representative for the Company, selling the Cholesterol Drug in Illinois.

PROBABLE CAUSE TO BELIEVE FEDERAL CRIMES WERE COMMITTED

The Conspiracy

17. Soon after joining the Company, MOFFETT entered into an agreement with others known and unknown, including at least Co-conspirators A, B, C, and D, all of whom worked as customer service representatives in the Patient Access Program.

18. The purpose of the conspiracy was to obtain insurance coverage for the Cholesterol Drug for patients who did not meet insurance plans coverage criteria. The conspiracy involved submission of false information to insurance plans by wire with the goal of causing insurance plans to pay the Pharmacy, which in turn would pay the Company, for the Cholesterol Drug.

The Scheme to Defraud

19. From at least January 2014 and continuing until at least February 2015, MOFFETT, with others known and unknown, devised and executed a scheme to defraud health insurance plans concerning coverage for the Cholesterol Drug.

20. MOFFETT and others known and unknown caused false information regarding diagnoses, clinical histories, and laboratory tests to be submitted to health insurance plans on prior authorization forms for the Cholesterol Drug.

21. MOFFETT either personally completed prior authorization forms with false information or caused others to complete the prior authorizations with false information. MOFFETT either sent the falsified prior authorizations or caused the falsified prior authorization forms to be sent to Patient Access Program in Massachusetts by fax or email or to health insurance plans by fax, email, or phone or to the Pharmacy by fax, email, or phone.

22. MOFFETT thereby caused health insurance plans to pay for prescriptions for the Cholesterol Drug for patients who did not meet the health insurance plans' coverage criteria. The Company received payment from the health insurance plans and in turn paid MOFFETT bonuses based on the prescription prior authorizations that he falsified or caused to be falsified. The following are three such patients.

Overt Acts in Relation to Patient 1

23. On or about February 27, 2014, MOFFETT met with the Physician Assistant in the Illinois Practice's Mattoon office regarding Patient 1. Patient 1 was not present. MOFFETT

obtained a prescription for Patient 1 from the Physician Assistant even though the Physician Assistant was not involved in Patient 1's treatment. Doctor A, who was treating Patient 1, did not sign any prescriptions and was not trained on or enrolled in the REMS program. The Physician Assistant signed a REMS enrollment form. At the same time, MOFFETT obtained a patient consent for disclosure of medical records that bears Patient 1's name and purported signature. According to Patient 1, the signature is not Patient 1's signature. MOFFETT caused the prescription, a statement of medical necessity, and the patient consent form to be faxed to Patient Access Program in Cambridge, Massachusetts.

24. On or about March 19, 2014, Co-conspirator A, an employee of the Company's Patient Access Program contacted Victim 1, Patient 1's health insurance plan, by phone. During the telephone call, Co-conspirator A falsely claimed to be employed by Doctor A. Co-conspirator A used the Physician Assistant's name and national provider number ("NPI"), but identified the Physician Assistant as a doctor. At Co-conspirator A's request, a representative of Victim 1 faxed a prior authorization form to the Company's fax number in Massachusetts.

25. On or about March 19, 2014, by e-mail, MOFFETT forwarded a prior authorization form for Patient 1 to the Manager at the Mattoon office of the Illinois Practice and provided answers to be inserted on the prior authorization form, (a) including a diagnosis of HoFH that Patient 1 did not have, (b) indicating a positive result on an diagnostic test for HoFH (skin fibroblast) that Patient 1 never had, and (c) referencing clinical records regarding Patient 1's parents that the Illinois Practice did not possess. The Manager completed the prior authorization as requested and, following MOFFETT's instructions, faxed the form to the Patient Access Program in Cambridge, Massachusetts, rather than to Victim 1.

26. Victim 1 later approved coverage of the Cholesterol Drug for Patient 1 based on the prior authorization containing false information provided by MOFFETT and ultimately paid $74,999 for the Cholesterol Drug.

27. The Company paid MOFFETT sales bonuses based on Patient 1's prescription.

Overt Acts in Relation to Patient 2

28. On or about September 24, 2014, MOFFETT obtained a prescription for the Cholesterol Drug for Patient 2 from Doctor B, and on or about September 25, 2014, MOFFETT caused a prior authorization for the Cholesterol Drug for Patient 2 to be faxed from Doctor B's Springfield office to Patient Access Program in Cambridge, Massachusetts. The prior authorization for Patient 2 has MOFFETT's handwriting on it, indicating a diagnosis of HoFH that Patient 2 did not have and attaching copies of treatment notes purportedly signed by Doctor B. The purported clinical notes have MOFFETT's handwriting on them. The handwriting says that Patient 2 had "xanthomas." The handwritten annotation, "xanthomas," appears next to a purported treatment observation of "xanthelasmas" on Patient 2's eyes. The reference to "xanthelasmas" does not appear in the clinical record maintained by the Illinois Practice for Patient 2, which Doctor B in fact signed digitally on September 27, 2014.

29. Also on or about September 25, 2014, MOFFETT emailed Co-conspirator B at the Patient Access Program in Cambridge, Massachusetts to alert Co-conspirator B to expect the prior authorization that includes the notation, "eye xanthomas."

30. On or about September 25, 2014, Co-conspirator B in Cambridge, Massachusetts, called Victim 2, the pharmacy manager for Patient 2's health insurance plan, and, using the prior authorization bearing MOFFETT's handwriting, obtained insurance coverage for the Cholesterol Drug for Patient 2. During the phone call, Co-conspirator B used Doctor B's name and NPI and claimed to work for Doctor B.

31. Victim 2 paid at least $651,144 for the Cholesterol Drug for Patient 2 in 2014 and 2015.

32. The Company paid Moffett sales bonuses based on Patient 2's prescription.

Overt Acts in Relation to Patient 3

33. On or about August 13, 2014, MOFFETT obtained a prescription for the Cholesterol Drug from Doctor B for Patient 3 and, in addition to emailing with Co-conspirator B in Cambridge, Massachusetts about the prescriptions, had the prescription sent to Co-conspirator B in Cambridge, Massachusetts by fax.

34. Victim 3, the pharmacy benefit manager for Patient 3's Medicare plan, initially denied the claim for service because the Cholesterol Drug had been prescribed for hyperlipidemia rather than for HoFH. Victim 3 sent a prior authorization form for the Cholesterol Drug. Victim 3's records reflect that, on August 14, 2014, it communicated by fax regarding Patient 3 using a fax number belonging to the Company in Massachusetts, rather than the fax number for Doctor B's office.

35. On August 14, 2014, after Victim 3 faxed information to the Company's fax number, Co-conspirator C, an employee of the Company's Patient Access Program, called Victim 3 with additional information regarding Patient 3. Victim 3's records state that a diagnosis of HoFH for Patient 3 was provided. On the call, Co-conspirator C claimed to be Doctor B's employee rather than an employee of the Company.

36. On September 3, 2014, Co-conspirator B called Victim 3 to inquire about the status of Patient 3's prescription. Co-conspirator B falsely represented that he was calling from Doctor B's office.

37. On September 11, 2014, Co-conspirator B (located in Massachusetts) contacted Victim 3 to withdraw the pending prior authorization for the Cholesterol Drug for Patient 3 and stated that a new prior authorization form would be faxed.

38. The Pharmacy received a fax, dated September 11, 2014, of a copy of Victim 3's prior authorization for the Cholesterol Drug, indicating that Patient 3 had diagnosis of HoFH.

39. Victim 3 paid for the Cholesterol Drug for Patient 3 in fall 2014.

40. In January 2015, Victim 3 again refused to cover the Cholesterol Drug for Patient 3 because Patient 3 did not have a diagnosis of HoFH.

41. On or about February 5, 2015, Doctor C (in the same practice as Doctor B) or a member of his staff submitted a prior authorization for the Cholesterol Drug for Patient 3 correctly stating Patient 3's diagnosis, which was not HoFH. Doctor C confirmed with Doctor B that Patient 3 did not have a diagnosis of HoFH.

42. On or about February 10, 2015, Victim 3 received a fax with a prior authorization for Patient 3 indicating a diagnosis of "272.4 272.0 Hyperlipidemia homozygous familial hypercholesterolemia." The prior authorization was purportedly signed by Doctor B.

43. Doctor B has not diagnosed Patient 3 as having HoFH.

44. On or about February 26, 2015, MOFFETT e-mailed Nurse A and Nurse B at Doctor B's office about Patient 3; he thanked them for speaking by phone with Co-conspirator D, a Company representative in Cambridge, Massachusetts, and instructed them "under diagnosis code don't put hyperlipidemia just put 272.0 HoFH . . . sorry its duplication but insurance companies suck."

45. On or about February 26, 2015, Co-conspirator D (located in Massachusetts) contacted Victim 3 by phone regarding Patient 3's prior authorization for the Cholesterol Drug.

46. On March 6, 2015, Victim 3 approved coverage of the Cholesterol Drug for Patient 3 based on information purportedly received from Doctor B, indicating a diagnosis of "hyperlipidemia" and "homozygous familial hypercholesterolemia" and ultimately paid roughly $471,499 to cover the Cholesterol Drug for Patient 3 in 2014 and 2015.

47. The Company paid MOFFETT sales bonuses for Patient 3's prescriptions.

CONCLUSION

48. Based on the foregoing, I submit there is probable cause to believe that MOFFETT committed the following federal crimes:

a. Wire fraud, in violation of 18 U.S.C. § 1343, on or about March 19, 2014, by fax regarding Patient 1;

b. Wire fraud, in violation of 18 U.S.C. § 1343, on or about September 25, 2014 by phone regarding Patient 2;

c. Wire fraud, in violation of 18 U.S.C. § 1343, on or about February 26, 2015 by phone regarding Patient 3; and

d. Conspiracy to commit wire fraud, in violation of 18 U.S.C. § 371, from at least January 2014 through March 2015.

Beth Ann Irvine
Assistant Special Agent in Charge
Health and Human Services,
Office of the Inspector General

Sworn and subscribed to before me this 11th day of May 2018, at Boston, Massachusetts.

Hon. Jennifer C. Boal
United States Magistrate Judge
District of Massachusetts